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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,407	12/26/2001	Larry Caldwell	TOPI-002CIP	3764

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,407	CALDWELL ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged applicants' amendment and copy of the declaration filed 12/18/2002, both filed 03/31/2008.

The finality of the previous office action mailed 12/18/2007 has been withdrawn, and new action on the merit has been issued as follows:

Claims 1-28 were previously presented.

Claims 19-23 have been canceled.

Claims 1-18 and 24-28 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claims 1, 6 and 11 recite that "NSAID only acts locally". The specification gives no guidance to one of ordinary skill in the art regarding formulation that permits the NSAID to acts only locally and does not permit any drug to reach the blood stream and to show some systemic effect. How topical formulation would be prohibited from reaching the blood stream since blood capillaries reach every point from the human body including the skin. The specification does not describe formulation that permits "topically applied NSAID that acts only locally".

The expression "topically applied NSAID that acts only locally" without partial or complete description of any formulation that does this function does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language "acts only locally" recited without any description of the formulation that enables this function does not meet the written description requirement for NSAID that acts only locally as one of ordinary skill in the art could not recognize or understand such a formulation from the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of topical formulations and applicants claimed expression represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed. The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-18 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of either one of the article by Pradalier et al. or the article by Cluff, each article combined with both of US 6,667,799 ('799) and US 5,318,960 ('960).

Pradalier et al. teaches NSAID including ibuprofen, diclofenac and indomethacin having significant effect to treat migraine (see the provided abstract).

Cluff teaches NSAID including ketoprofen and ibuprofen as being beneficial as abortive treatment of migraine (see table 4, and the paragraph preceding table 4 of the provided article).

However, Pradalier and Cluff do not explicitly teach topical application of NSAID that acts locally.

US '960 teaches composition for pain relief comprising NSAIDs that when applied to the skin of the patient will deliver pain relieving substance directly to the afflicted area of the body, thus alleviating the side effects caused by systemic application and allowing NSAID to be delivered precisely to the body at specific area of pain (abstract; co1.2, lines 5-9, 61-65). Examples of NSAID include indomethacin, ketoprofen, diclofenac, and ibuprofen (col.3, lines 50, 53, 56; col.6, lines 30, 58).

US '799 teaches method for treatment of host suffering from headache pain with topical application of local anesthetic applied to keratinized skin proximal to target nerves associated with the headache pain, usually to the supraorbital or occipital regions of the head, so the drug penetrates the skin to block conduction in the target

nerves and provides pain relief to the host (abstract; col.2, lines 41-67; col.3, lines 1-9; col.5, lines 18-29, claims). The drug applied topically in formulation comprising cream, plaster or patch (col.4, lines 12-15, 55-57, 66-67; col.5, lines 59-60). The method is used to treat migraine headache (col.6, lines 15-16, 30-35). This method of application of headache pain relief composition to the skin proximal to target nerves associated with the headache is convenient method that is well tolerated by the patient and provides relief of pain shortly after application of the composition (col.6, lines 43-46). This method is improvement over systemic applications of NSAID to treat headache that provides undesired systemic side effects (col.1, lines 17-31).

Therefore, at the time of the invention, NSAIDs including those claimed by applicants were known in the art to be effective and beneficial to treat migraine as taught by Pradalier and Cluff, and NSAID were also known to be delivered topically at the site of pain to alleviating the side effects caused by systemic application and allowing NSAID to be delivered precisely to the body at specific area of pain as taught by US ‘960, and furthermore, US ‘799 treated migraine by topical delivery of pain relief composition to keratinized skin proximal to target nerves associated with migraine headache, usually to the supraorbital or occipital regions of the head, so the drug penetrates the skin to block conduction in the target nerves and provides pain relief drug to the host.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat migraine using NSAID as disclosed by any of Pradalier or Cluff, and deliver NSAID topically directly to the site of pain to alleviating the side

effects caused by systemic application and allowing NSAID to be delivered precisely to specific area of pain as taught by US '960, and further deliver NSAID to keratinized skin proximal to target nerves associated with migraine headache specifically to the supraorbital or occipital regions of the head, so the drug penetrates the skin to block conduction in the target nerves and provides pain relief to the host by convenient well tolerated method as disclosed by US '799, with reasonable expectation of treating migraine headache by topically applying NSAID to keratinized skin proximal to target nerves associated with migraine headache to the supraorbital or occipital regions of the head to block conduction in the target nerves and effectively relief migraine without having undesired systemic side effects of NSAID wherein the method is convenient and well tolerated by the patient and provides relief of pain shortly after application of NSAID.

Response to Arguments

6. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's declaration filed 12/10/2002, and resubmitted on 03/31/2008 is moot in view of the new ground of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611